K091688

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: **AG DIGITAL Technology Corp.**

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Contact: Frank Chou / manager

MAR - 2 2010

2. Device Name :

Trade Name: **A-GRIX Resorbable Bone Void Filler**

Common Name: **Bone Void Filler**

Classification name filler, bone void, calcium compound

3. DEVICE CLASS **A-GRIX Resorbable Bone Void Filler** have been classified as

Regulatory Class: II

Product Code: MQV

Panel : Orthopedic

Regulation Number: 21CFR 888.3045

4. Predicate Device: The predicate device is the

- **Osteo-G bone void filler (K031319)** marketed by **ASPINE USA, INC.**

5. Device Description: The **A-GRIX Resorbable Bone Void Filler** contains 1 bottle of solid phase and 1 bottle of mixing solution. The solid phase is composed of high purity medical grade calcium sulfate hemihydrate fine powder and different size calcium sulfate granules.

Because of the special treated granules, the dissolving of **A-GRIX Resorbable Bone Void Filler** would be longer than other products and closer to the new bone formation. Besides, the different granule size could make it be easy to be filled into the bony defect. When mixed according to the directions, **A-GRIX** forms the biodegradable, biocompatible and

radiopaque paste or putty, and can then be digitally applied directly or by injection into the defect site.

A-GRIX Resorbable Bone Void Filler is osteoconductive which acts as a scaffold and facilitate new bone growth. After implanted, it will be resorbed in approximately 90 days and replaced by new bone during the healing process. This product is supplied sterile for single patient use.

6. Intended Use:

A-GRIX Resorbable Bone Void Filler is indicated to fill bony void or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bone structure. These defects may be surgically created osseous defects created from traumatic injury to the bone. The bone void filler resorbs and is replaced with new bone during the healing process. A-GRIX Resorbable Bone Void Filler may be used at an infected site. When used in the spine, the device is limited to posterolateral fusion procedures only.

7. Performance Summary:

The device conforms to applicable standards includes ISO 10993 series : Biological evaluation of medical devices , ASTM F2224-03 : Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants & ANSVAAMI/ISO 11137 Sterilization of Health Care Products - Radiation Sterilization.

8. Conclusions:

The **A-GRIX Resorbable Bone Void Filler** has the same intended use and technological characteristics as the **Osteo-G bone void filler (K031319)** marketed by **ASPINE USA, INC.**. Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **A-GRIX Resorbable Bone Void Filler** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 2 2010

AG Digital Technology Corporation
% Harvest Consulting Corporation (USA)
Ms. Jennifer Reich
Senior Consultant
2904 North Boldt Drive
Flagstaff, Arizona 86001

Re: K091688
Trade/Device Name: A-GRIX Resorbable Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: February 5, 2010
Received: February 12, 2010

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: **A-GRIX Resorbable Bone Void Filler**
AG DIGITAL Technology Corp.

Indications For Use:

A-GRIX Resorbable Bone Void Filler is indicated to fill bony void or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bone structure. These defects may be surgically created osseous defects created from traumatic injury to the bone. The bone void filler resorbs and is replaced with new bone during the healing process. A-GRIX Resorbable Bone Void Filler may be used at an infected site. When used in the spine, the device is limited to posterolateral fusion procedures only.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091687